

REMARKS

The Examiner has imposed a Restriction Requirement under 35 U.S.C. § 121 as follows, requiring election of one of the following groups of claims for prosecution on the merits, each of which is alleged to encompass a separate invention:

- I. Claims 1-8, drawn to a dosage regimen for administering tramadol to a patient comprising administering about 75 mg-125 mg of tramadol in a controlled release dosage form for about 4-10 days, then about 175-225 mg of tramadol for about 4-10 days and then about 275 mg-325 mg of tramadol for at least one day, classified in class 514, subclass 620;
- II. Claims 9-16 and 27-28, drawn to a dosage regimen for administering tramadol to a patient comprising administering about 100 mg of tramadol in a controlled release dosage form for about 1-7 days, then about 200 mg of tramadol for about 8-14 days and then about 300 mg of tramadol for at least one day, on day 15 and thereafter, and kits comprising said product, classified in class 514, subclass 567;
- III. Claims 17-21, drawn to a dosage regimen for administering tramadol to a patient comprising administering about 175 mg-225 mg of tramadol in a controlled release dosage form for about 4-10 days, then about 275-325 mg of tramadol in a controlled release dosage form once a day for at least one day and optionally thereafter, classified in class 514, subclass 553; and
- IV. Claims 22-26 and 29-30, drawn to a dosage regimen for administering tramadol to a patient comprising administering about 200 mg of tramadol in a controlled release dosage form for about 1-7 days, then about 300 mg of tramadol for at least one day and optionally thereafter, and kits comprising said product, classified in class 514, subclass 567.

The applicants hereby elect with traverse Claims 1-8, the subject matter of Group I. Applicants fully reserve the right to prosecute the subject matter of the non-elected claims in related applications. Applicants reserve the right to petition from the restriction requirement under 37 C.F.R. § 1.144.

Each of claims 1-26 recite a dosage regimen for administering tramadol to a patient, while claims 27-30 recite kits for the administration of a dosage regimen for administration of tramadol. In the Restriction Requirement, the Examiner has not distinguished between claims which recite dosage regimens and claims which recite kits, but instead has distinguished between claims which recite dosage regimens having different steps and end points. Applicants respectfully submit that a search of the art for the tramadol dosage regimen of Group I, recited in claims 1-8, will also yield the prior art, if any, for the tramadol dosage regimens and kits of Groups II-IV, recited in claims 9-30. Accordingly, Applicants respectfully request that the four groups be examined together.

The MPEP states that restriction is proper only when (1) the inventions are independent or distinct as claimed; and (2) there is a serious burden on the Examiner to search and examine the claims to the independent or distinct inventions. See MPEP § 803. As discussed above, the claims of the present invention recite dosage regimens for administration of tramadol and kits for the administration of a dosage regimen for administration of tramadol. Applicants respectfully submit that the claims of Groups I-IV are related, and examination of the claims of each of Group I-IV would not be unduly burdensome. The Examiner's attention is directed to Section 803 of the MPEP:

If the search and examination of an entire application can be made without serious burden, the examiner must examine it on the merits, even though it includes claims to independent or distinct inventions. (Emphasis added)

In view of the foregoing, Applicants respectfully request that the restriction requirement be withdrawn. Entry of the remarks made herein is respectfully requested.

No fee is believed to be due for this response. However, should any fee be required, please charge such fee to Duane Morris Deposit Account No. 04-1679.

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Respectfully submitted,



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